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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,537	08/10/2001	Hiroshi Tomiyama	TAN-293	4717

7590

09/23/2003

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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/925,537

Applicant(s)

TOMIYAMA ET AL.

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 17-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: .  |

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### **DETAILED ACTION**

Claims 1-4,17-28 are pending in application

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The following office action is a responsive to a provisional election which was made with traverse to prosecute the invention of Group I, claims 1-4 and 17-28 in Paper No. 8. The response has the following effect:

1. Claims 1-4 and 17-28 of Group I are prosecuted by the examiner.

Claims 8, 29-60 are withdrawn. Claims 5-7 and 9-16 are cancelled by preliminary amendment.

2. The responsive is contained herein below.

Applicant's election with traverse of Group I, claims 1-4 and 17-28 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that all claims contain the limitation of non-mucin type synthetic compounds. That different claims are drawn to a method of making the compounds or methods of using the compounds should be a basis for restriction. This is not found persuasive because the inventions have divergent subject matter and different classification.

The requirement is still deemed proper and is therefore made FINAL.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, claim a compound of general formula (1), (2), (3) and (4), respectively. Each

of the general formulas contains the structural group or moiety  $\text{---}\overset{\text{Q}}{\underset{\text{||}}{\text{C}}}\text{---}$ , where Q is H or oxygen. However, this structural moiety or group renders the claim confusing and indefinite, because when Q is hydrogen, the structural moiety or group would represent a double bond between carbon and hydrogen. But, since hydrogen can only form one bond, a double bond cannot be formed between carbon and hydrogen.

Claims 1, 2, 3, 17-28 recite the phrase "non-mucin type synthetic compounds or it's carrier conjugated compounds". However, this phrase "carrier conjugated compounds" renders the claim indefinite, because this phrase or terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what compounds are considered carrier conjugated compounds.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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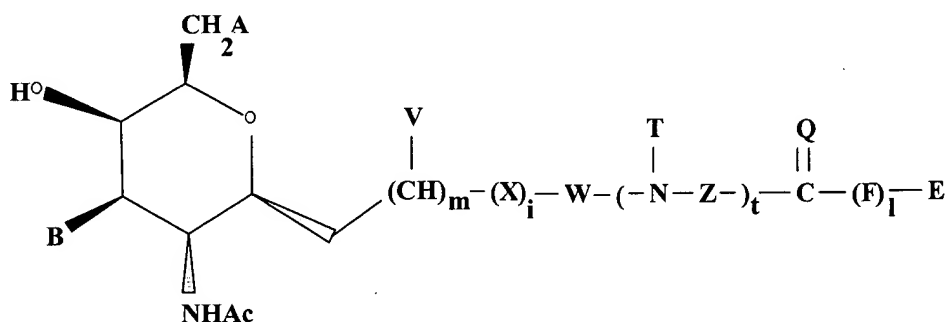
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 2 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Cipolla et al.

(Tetrahedron Asymmetry (2000), 11(1), 295-303).

In claim 2, applicant claims a compound of general formula (2),



wherein A, B, T, X, Q, V, W, Z, i, m, and t have above-mentioned meanings; E

represents pharmaceutically acceptable carrier compounds; l is 0 or 1; ..... Cipolla et al.

disclose applicant's claimed compound of general formula (2) wherein A represent OH, B = OH, m = 0, i = w = t = 0, Q = O and E represents a pharmaceutically acceptable carrier compound, and l is 0. Cipolla et al. compound is named D-glycero-L-gluco-2-Nonulose, 5-(acetylamino)-4, 8-anhydro-1,3,5-trideoxy- (see compound 16, page 298). Claim 26 which is drawn to non-mucin type synthetic compounds or carrier conjugated compounds thereof of claim 2, wherein both A and B are OH, is also anticipated by this rejection. It should be noted that the examiner considers the methyl group an acceptable carrier compound.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

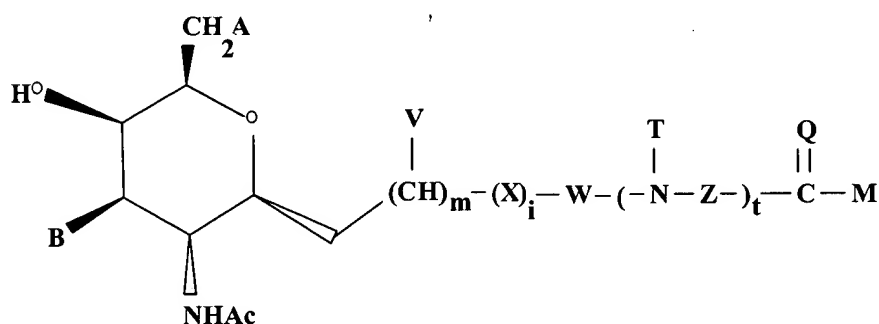
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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al.

(US 5,977,079).

In Claim 1, applicant claims a compound of general formula (1),



wherein A represents OH or sialic acid ..... ; non-mucin type synthetic compounds or it's carrier conjugated compounds, which have above mentioned compounds as a core structure of antigen.

Good et al. teach a subgenus that is fully embraced by the instant claim. Good et al. disclose in fig. IG (sheet 7, compound 35) a subgenus wherein in X represents a covalent bond and Y represents a radical of the general formula  $-A-Z$  wherein A is  $-(CH_2-CR_1-G)_n-$  wherein n equal 1,  $R_1$  is hydrogen, G is hydrogen and Z is  $-C(O)OR_2$  wherein  $R_2$  is hydrogen (col. 7, lines 41 to 60). In addition, Good et al. disclose that such a carbohydrate can be used as xenoantigen (see col. 6, lines 63-64).

Good et al. fail to recite a specific compound, but suggest a compound that read on the claimed invention (fig. IG, sheet 7, compound 35 and col. 7, lines 41 to 60).

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared any compound suggested by the subgenus of Good et al., in order to use them as antigens.

One having ordinary skill in the art would have been motivated, to prepare any compound of a subgenus with a reasonable expectation that the compounds would have the utility of the subgenus as a whole. Therefore one skilled in the art would have been motivated to make specific compounds of the subgenus of Good et al. in order to use them as antigens. It should be noted that claim 21 which is a limitation of claim 1 is also encompassed by this rejection.

*Allowable Subject Matter*

The following is an examiner's statement of reasons for allowance: The examiner has found claims 3 and 4 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record, provided that the 112 rejections are overcome. Claims 17-20,23,24,25,27,28 to be unobvious over the prior art of record and therefore may be allowable over the prior art of record, provided that the 112 rejections are overcome and these claims do not depend on a rejected claim or are written in an independent acceptable form. The present invention relates to a compound of a given general formula. The very relevant prior art document to this invention (US 5,977,079) discloses similar compounds of the given formula.

However, though the compounds of the present invention are similar to the compounds of the prior art, they possess structural differences that are unobvious to those of the prior art.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

September 11, 2003

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1200